Small Tobacco Product Manufacturers: Outline of Issues

FDA Center For Tobacco Products
Tobacco Manufacturers Stakeholders Meeting
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Small Manufacturers' Issues

- Should not be analogous to drug/device regulation
- Urgent need for responsive interactive Office to Assist Small Manufacturers
- Need for "neutral" regulator not seeking elimination of tobacco from marketplace
- Risk of severe economic injury to small manufacturers
- FDA should seek additional information concerning tobacco product manufacturing from STPMs
- Regulatory obstacles to innovation of potentially safer (modified risk) products (smokeless)
- Different commercial and policy agendas based on company size
- Regulations must take into account the unintended consequences for STPMs in a "one size fits all" regulatory structure

Different than Drug/Device Regulation

- FDA regulation of new drug/device development resulted in gradual escalation of costs of development, manufacturing and marketing

- Majority of smaller pharmaceutical/device companies driven **out of business** with resulting loss of jobs; higher cost to US consumers

- Small companies more sensitive to cost of regulatory compliance

- This would result in fewer products for consumers and a loss of jobs

Office to Assist STPMs

- Small tobacco product manufacturers (STPMs) defined as < 350 employees
- FDA required to create Office to Assist STPMs and provide technical (non-financial) support

  The Secretary shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this Act. *Sec. 901*

- FDA should request designation in electronic registration; identify small businesses
- ***Need assistance to ensure compliance***
  - ***Infrastructure for discrete small business office***
  - ***Same "assistance" given to everyone; need to limit office assistance to small businesses***
  - ***Staff required who are technically qualified or are willing to learn about tobacco manufacturing***

Need for "Neutral" Regulator

- "Schizophrenic" nature of Statute
  - Continue to permit sale of tobacco products to adults (Sec. 3(7))
  - Impose appropriate regulatory controls (Sec. 3(8))
  - Promote cessation to reduce disease risk

- Historic disagreement between FDA and industry beginning before *Brown v. Williamson*.

- Conflicting commercial interests and within FDA between pharmaceuticals (nicotine replacement)(CDER) and tobacco (CTP)

- Agency reassurance in prior meetings should match actual action taken

- How can impartial balance be maintained?

- What is meaning of "arbitrary and capricious" review standard in this circumstance?

Risk to Small Manufacturers

- Early estimates of basic testing (Hoffman analytes) could cost between $45,000-$75,000 per product
  - Testing costs increase dramatically based on methodology and number of ingredients
  - List includes compounds already approved for use in foods and drugs
  - Will data from testing be used (e.g., Canadians done little with data)

- GMP methodology unknown and impractical for tobacco manufacture; use of food-related HACCP more appropriate and better defined

- Small tobacco makers lack economic resources and technical, scientific or regulatory staff to meet anticipated GMP standards if template even vaguely resembles GMPs for drugs or devices
  - FDA requires first-hand production knowledge before tackling GMP rules
  - Tobacco is food-type commodity
  - Drug or device standards unnecessary; impractical
  - FDA could eliminate small-business if requirements too rigorous

FDA Needs Additional Information

- FDA needs first-hand information concerning:
  - How tobacco leaf is cultivated/grown
  - How tobacco leaf is sold
  - How tobacco products are made
  - Role of blender
  - How finished products are sold
- Suggestions to accumulate information
  - Visit farmers, blenders, component suppliers and makers of finished products
  - Meet with *ad hoc* industry working groups
  - Hire staff who worked in all relevant industry segments
  - Hire from TTB/USDA; or utilize inter-agency working group

Risk to Innovation

- Core of FSPTCA is reducing toxicity of tobacco products
- Small business sector uniquely positioned to innovate – more nimble, less risk-adverse; able to develop processes quickly
- FDA cooperation/interaction essential
- Regulatory hurdles to modified-risk products can discourage development of safer-use products (e.g., snus and smokeless alternatives)
- Many options exist to encourage innovation (e.g., acknowledgment of substantial equivalence (SE) of smokeless, alt. products, etc.)

STPMs: Specific Issues

- Engage with industry to define 'substantial equivalence'
  - Proposed rule needed immediately
  - Definition can encourage innovation and use of safer products
  - Allow use of others' "master tobacco files" if detailed ingredient analysis required (by manuf. without full product line pre-2007)
  - Draft regulations needed immediately with input for accurate small business regulatory flexibility analysis

- Issue separate 'templates' for product labeling; provide explicit easy to understand labeling guide

- Engage with industry about application of "List of Harmful and Potentially Harmful Constituents;" reduce and prioritize initial list to permit access to affordable testing; list can always be expanded

- Issue clarifying definitions/examples of tobacco "adulteration" and "misbranding" before initiating manufacturer facility inspections

STPM: Specific Issues (cont.)

- Modified Risk Tobacco Product application process lacks clarity; requires clear timeline and process
- Facilities on Native American sovereign lands require specific regulatory analysis
- Thinking regarding GMP/HACCP requirements should be released in draft form, or in industry discussions, so STPMs can begin to prepare

STPMs: Conclusion

- Require consistent/meaningful framework for good-faith dialogue; sharing of ideas
- How will FDA ensure impartiality in implementing regulatory structure?
- We commit to meet you more than half-way
- What is FDA prepared to do to insure that its actions match its reassuring rhetoric?